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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/467,333 12/20/99 DOBROZSI

D 7804

027746 HM12/0821  
THE PROCTER & GAMBLE COMPANY  
PATENT DIVISION  
HEALTH CARE RESEARCH CENTER  
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EXAMINER

NGUYEN, H

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

08/21/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Applicati n No. 09/467,333	Applicant(s) DOBROZSI ET AL.	
	Examiner Helen Nguyen	Art Unit 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 June 2001 .
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
    If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
    a) ☐ All    b) ☐ Some \* c) ☐ None of:  
        1. ☐ Certified copies of the priority documents have been received.  
        2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
        3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
    \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
    a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-941)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other:  |

### DETAILED ACTION

The claimed priority of this application to US Provisional Application No. 60/156,540 and 60/115,378, is acknowledged.

The amendment of paper no. 6 is acknowledged.

Claims 1-3 have been canceled.

Claims 4, 9-11 and 15 have been amended.

Claim 21 have been added.

Claims 21, 4-20 are presented for examination.

The references '965, '660 and '446 rejection of claims 1-20 of record under 35 U.S.C. 102 (b), are hereby withdrawn. However, the Examiner will maintain the 102 rejection over reference '543.

### Claim objection

Claim 5 is objected to because of the following informalities: the term "terbuty" is misspelled. It appears to be a typographical error. Does Applicant intend tert-butyl?

Appropriate correction is required.

### Claim rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21, 4-20 are rejected under **35 U.S.C. 102(b)** as being anticipated by

Gallow-Torres et al. (US Patent No. 4,310,543).

OK  
moot  
canceled  
cl. 5 & new  
cl. 23 recited a correct spelling,

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Gallow-Torres et al. teach a pharmaceutical composition comprising a drug (see abstract), solvent agents including polyethylene glycol (PEG) (see abstract), and reducing agents including bisulfite, thiourea, and tert-butyl hydroquinone (TBHQ) (see column 3, lines 30, 34, 35). 0.025 to 2% weight of active drug (column 2, lines 24-25), about 90 to 99.9% weight of solvent (column 3, lines 7-8), and about 0.5% of reducing agent (column 3, line 37) are specified. Oral administration is disclosed (column 3, line 41). *Water is disclosed (table, column 6)*

As to the claimed properties, they must be possessed by the anticipated compositions because they are the same as those claimed.

As to Applicant's argument that ascorbic acid is not a reducing agent, the reference teaches bisulfite, thiourea, and tert-butyl hydroquinone (TBHQ), which Applicant recites as reducing agents in claim 5.

*Reducing agent*  
1. No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is (703) 605-1198. The examiner can normally be reached on M-F (9:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, Edward J. Webman can be reached at (703) 308-4432 or her supervisor, Minna Moezie can be reached at (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Helen Nguyen  
Patent Examiner

August 9, 2001



EDWARD J. WEBMAN  
PRIMARY EXAMINER  
GROUP 1500